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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,067	12/13/2004	Carsten Pilger	MG-2519	2721

23416 7590 05/23/2007
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EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
05/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/518,067	PILGER ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7 and 14-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 14-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-6 and 8-14 have been cancelled. Claims 7 and 15-19 are pending and under examination. Applicant's amendment has necessitated a new ground of rejection.

Comment: It appears that claim 7 is written is a Jepson-style format but the "wherein the improvement comprises..." phrase is missing.

In claim 7, line 14, it appears that "homogenous" should be hemogenous in order to be self-consistent.

Withdrawn rejections:

Claim 7 was rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of stroke, does not reasonably provide enablement for prophylaxis of stroke. Applicant has amended the claim and the Examiner withdraws the rejection.

Claim 7 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Applicant has amended the claim to read upon known cerebral medicaments and argued persuasively that one of ordinary skill in the art would know the amount and duration of action of the known medicament. The Examiner withdraws the rejection.

Claim 7 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant

regards as the invention. Applicant has amended the claim and the Examiner withdraws the rejection.

Claim 7 was rejected under 35 U.S.C. 102(b) as being anticipated by Fishman (US 5,228,434). Applicant has amended the claim and the Examiner withdraws the rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 14-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 7 introduces new matter as it states: "the cerebral homogenous medicament consisting of a material other than oxygen."

Ex parte Grasselli 231 USPQ 393 (Bd. App. 1984) shows that negative limitations which do not appear in the specification as originally filed and which introduce new concepts violate the description requirement of 35 USC 112, ¶1.

Ex parte Grasselli states:

"Despite appellants' arguments to the contrary, we agree with the examiner's position of record that the negative limitations recited in the present claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112. In re Anderson, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973). The examiner's distinctions between the present case and the prior decisions cited by appellants are correct and we adopt his position in that regard as our own. It might be added that the express exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitations do, in fact, introduce new concepts."

The findings of Ex parte Grasselli are discussed also in Ex parte Parks, 30 USPQ2d 1234 (BPAI 1993)]. Parks notes that the CAFC upheld the decision in Grasselli in 1984.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 14-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 recites: "the cerebral homogenous medicament consisting of a material other than oxygen." It is unclear to the Examiner if this means that the medicament cannot contain an oxygen atom or if the medicament

cannot contain oxygen gas. Claims 14-19 are rejected as being indefinite because they are based on an indefinite base claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7 and 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petzelt et al. (WO 00/53192) in view of Fishman (US 5,228,434) as evidenced by Marshall et al. Neurosurgery, 1983, 13(4), 412-414.

Applicant claims a method of treating a patient with a combination medicament comprising gaseous xenon and a cerebral hemogenous medicament.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Petzelt et al. teach the use of xenon or xenon gas mixtures for neurointoxications, broadly including craniocerebral trauma, where the amount of xenon administered can be from 5 to 90% by volume or the more narrow range of 5 to 30 % by volume (Abstract; claims 1-13). Petzelt et al. teach inhalation methods (Page 8, third paragraph). Thus, Petzelt et al. teach the instant patient population and inhalation of gaseous xenon mixtures in the instantly claimed amounts.

Marshall et al. teach thiopentone for use in treating brain swelling (Abstract).

Fishman teach a mixture consisting of from 60 to 78.5 mole percent stable xenon, from 19.5 to 38 mole percent oxygen and from 2.5 to 20.5 mole percent helium (Claim 1). Methods of making and methods of using the gas mixture are disclosed (Column 3, lines 14-42 and column 5, lines 8-36) and use of the gas mixture in combination with intravenously introduced methyl-atrophine bromide, thiopentone and fentanyl (Column 5, lines 10-13). Fishman disclose a composition comprising 60-78.5 mol% xenon as well as the instant limit of 65 mol% (claims 1 and 4). Fishman broadly establish using the xenon gas mixture during surgery, which could as well be brain surgery (column 5, lines 8 and 9). Fishman establish the use of xenon gas mixtures in combination with other medicaments such as the cerebral hemogenous medicament thiopentone in surgery.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

1. Petzelt et al. do not expressly teach co-administration of a cerebral hemogonous medicament.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to co-administer of a cerebral hemogenous medicament, such as thiopentone, as suggested by Fishman, to treat cerebral trauma, like brain swelling, as taught by Marshall et al., in the method of Petzelt et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because the Petzelt et al. teach the use of xenon gas mixtures for use in treating brain trauma and the art teaches using xenon in combination with medicaments useful for the treatment of brain trauma. The results are predictable. It is immediately obvious to one of ordinary skill in the art to combine the methods taught in the art to produce the instant invention. The determination of a specific volume of xenon from 5-60% or 5-50% or 5-40% or 5-30% or 5-20% volume is merely a matter of routine optimization of the amounts taught by Petzelt et al. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." And; "The results of ordinary innovation are not the subject of exclusive rights under the patent

laws." KSR INTERNATIONAL CO. v. TELEFLEX INC. ET AL. pgs. 12, 24; 550 U. S. ____ (2007)"

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claim 7 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7 and 9 of copending Application No. 10/517,722. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims 7 and 9 are embraced by the copending claims 7 and 9.

The copending application teaches a method of treating a patient with xenon or a xenon containing gas mixture in a subanesthetic amount of xenon wherein what is administered to the patient contains no more than 70% by volume of xenon for the treatment of spasms, vasospasms, cerebral vasospasms, improvements of blood flow, impairments of blood flow in the brain, cognitive impairments, stroke etc...selecting as a patient someone having such condition and administering the xenon medicament to the patient (Claim 7). The copending application teaches the inclusion of an NO source (Claim 9). The Examiner interprets NO to be a hemogenous medicament can be administered orally.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the copending application embraces the instant claims by

having a method with xenon in the exact same proportions and a medicament, NO, for the treatment of, for example, impairments of blood flow in the brain. One of ordinary skill in the art would have recognized the obvious variation of the instant application over the copending application based on the overlapping scope of the claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2) Claim 7 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6 and 7 of copending Application No. 10/517,723 (Notice of allowability sent 1/25/07). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace or are embraced by the copending claims.

The copending application teaches a method of treating a patient with xenon or a xenon containing gas mixture in a subanesthetic amount of xenon wherein what is administered to the patient contains no more than 70% by volume of xenon for the treatment of, for example impairments of blood flow in the brain and cognitive dysfunction, selecting as a patient someone having such condition and administering the xenon medicament to the patient (Claims 6 and 7). The copending application teaches the inclusion of an NO source. The Examiner interprets NO to be a hemogenous medicament that can be administered orally.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the copending application embraces the instant claims by having a method with xenon in the exact same proportions and a medicament, NO, for

the treatment of, for example, impairments of blood flow in the brain. One of ordinary skill in the art would have recognized the obvious variation of the instant application over the copending application based on the overlapping scope of the claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments:

Applicant asserts that the amended claims are now patentably distinct from the copending applications. The examiner cannot agree. The same xenon gas mixtures, same type of conditions to be treated and a cerebral hemogenous medicament, nitric oxide, are disclosed in the copending applications. It remains obvious as discussed in more detail above.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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